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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,892

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Shigeru Hiramoto

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EXAMINER

MI, QIUWEN

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/501,892	<b>Applicant(s)</b> HIRAMOTO ET AL.	
	<b>Examiner</b> QIUWEN MI	<b>Art Unit</b> 1655	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's amendment in the reply filed on 9/14/07 is acknowledged.

The previous 112, 1<sup>st</sup> scope enablement rejection, and 112, 2nd rejection over claims 19-24 are withdrawn due to Applicant's amendment to the claims by specifying the disease type to "gastritis, gastric ulcer or duodenal ulcer associated with *Helicobacter pylori*". In addition, the attachments from Hosking et al and Sung et al are convincing for withdrawing the two rejections.

### **Claims Pending**

Claims 25-29 are new added. Claims 1-14 are cancelled. Claims 15-29 are pending.  
Claims 15-29 are examined on the merits.

### **Claim Rejections –35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-18, 22-24, 25, and 26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (US 6,329,002), in view of Kim et al (US 6,627,238).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 11/20/2007, repeated below, slightly altered to take into consideration Applicant's amendment filed on 2/20/08. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Kim et al (US 6,329,002) teach a method of preventing and/or treating disorders associated with infection by *Helicobacter pylori* with nutritional food in combination with an active strain of a living microorganism in an amount effective to inhibit or prevent the growth of *H. pylori* in a human stomach (claim 8). Kim also teaches a method for prevention and/or treatment of gastritis, duodenal and gastric ulcers caused by infection from *Helicobacter pylori* (see Abstract). The living organism being of lactic acid origin is selected from the group consisting yogurt, buttermilk, cream cheese, and ice cream (claim 12). Further more, as evidenced by Wikipedia online, all major dietary carbohydrates contain glucose, and D-glucose and L-glucose are the two isoforms of glucose, thus a bagel would contain sugar D-glucose. Also as evidenced by Wikipedia online, casein is the predominant phosphoprotein that accounts for nearly 80% of proteins in milk and cheese, and lactose is a sugar which is found most notably in milk. Therefore, any one who eats a toast bagel (nutritional food) with a yogurt (contains live strains of living microorganism *Lactococcus* sp HY 49, *lactobacillus casei* HY 2782, and *Bifidobacterium longum* HY 8001), and drinks milk (inherently contains lactose and casein) reads on treating disorders associated with infection by *Helicobacter pylori*.

Kim et al (US 6,329,002) do not teach the claimed amount of browning reaction product.

Kim et al (US 6,627,238) teaches that browning reaction that contains sugars such as glucose, fructose, galactose, lactose, and free amino groups from proteins of microorganisms (buttermilk, cream cheese) (col 2, lines 4-10) occurs in foods heated by microwave, food containing a dough crust heated in a conventional oven, and food to be baked (col 1, lines 30-35; col 2, lines 50-55) [which reads on any one who eats a toast bagel (nutritional food) with a yogurt (contains live strains of living microorganism *Lactococcus* sp HY 49, *lactobacillus casei* HY 2782, and *Bifidobacterium longum* HY 8001), and drinks milk (inherently contains lactose and casein)].

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to consume the browning reaction product, a toasted bagel, in the invention of Kim et al (US 6,627,238), as a nutritional food, to combine with an active strain of a living microorganism, yogurt, and nutritional food milk, in the invention of Kim et al (US 6,329,002), to prevent and/or treat disorders associated with infection by *Helicobacter pylori*. Since the bagel/yogurt, and milk consumption varies according to people's appetite, age, and weight, the amount of browning reaction product as claimed is a result-effective adjustment in conventional working parameter, which is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan.

Applicant argues that "In the first place, Kim et al. (U.S. 6,329,002) and Kim et al. (U.S. 6,627,238) describe nothing about a toast bagel. Kim et al. (U.S. 6,329,002) describe the cream cheese not as a substance including a living microorganism but as a nutritional food (see claims 8

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and 12). In this context, Kim et al. (U.S. 6,329,002) only disclose a conventional food of lactic acid origin (i.e. cream cheese) in combination with the specific active strain of living microorganism (i.e. *Lactococcus* sp. HY 49, *Lactobacillus casei* HY 2782 and *Bifidobacterium longum* HY 8001) (page 6, 4<sup>th</sup> paragraph).

It is true that none of the two Kim references mention a toast bagel. However, Kim et al (US 6,627,238)'s teaching clearly reads on a toast bagel. It is the Examiner's opinion that cream cheese contains the active strains of living microorganism. Even if it does not, as the Abstract explicitly teaches "live strains of *Lactococcus* sp. HY 49, *Lactobacillus casei* HY 2782, and *Bifidobacterium longum* HY 8001 maintained in nutritious foods, such as yogurt, imbue them with prophylactic and/or therapeutic properties. Such foods are beneficial in the prevention and/or treatment of gastritis, duodenal and gastric ulcers caused by infection from *Helicobacter pylori*". Therefore, one of ordinary skill in the art at the time the invention was made to consume the browning reaction product, a toasted bagel, in the invention of Kim et al (US 6,627,238), as a nutritional food, to combine with an active strain of a living microorganism, yogurt, and nutritional food milk, in the invention of Kim et al (US 6,329,002), to prevent and/or treat disorders associated with infection by *Helicobacter pylori*.

Applicant argues that "It is clear that the specific active strain of living microorganism (*Lactococcus* sp. HY 49, *Lactobacillus casei* HY 2782 and *Bifidobacterium longum* HY 8001) is indispensable for the invention disclosed in Kim et al. (U.S. 6,329,002) (see column 4, lines 17-36). In fact, it is demonstrated in Example 6 that control group (fed yogurt only) does not show effective prevention (please see Fig. 1)" (page 6, 5<sup>th</sup> paragraph).

This is not found persuasive. Example 6 is used to “provide evidence that even the active strains, by themselves, proved an unexpected prophylactic effect which is greatly improved by the addition of *H. pylori*-antibodies”. For that reason, yogurt was used as a control in that example.

Applicant argues that “In addition, the specific strain of living microorganism should be active in the invention of Kim et al. (U.S. 6,329,002). That is, Kim et al. (U.S. 6,329,002) never teach or suggest to heat any food. Also, it is described that “it is a general object of this invention to provide a food for “general human consumption, comprising a food stored at temperature in the range of about -45°C but no more than 45°C” (see column 4, lines 37-40). Therefore, Kim et al. (U.S. 6,329,002) does not teach or suggest anything about the product of browning reaction” (page 6, last paragraph bridging page 7).

It is true that the yogurt or cheese wherein the active strains of living organisms are maintained will be stored at temperature in the range of about -45°C but no more than 45°C. Applicant is reminded that it is the bagel that is being toasted, not the yogurt or cream cheese.

Claims 15-29 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (US 6,329,002), in view of Kim et al (US 6,627,238), and further in view of Kodama et al (US 2001/0044120).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 11/20/2007, repeated below, slightly altered to take into consideration Applicant’s

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amendment filed on 2/20/08. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Kim et al (US 6,329,002) teach a method of preventing and/or treating disorders associated with infection by *Helicobacter pylori* with nutritional food in combination with an active strain of a living microorganism in an amount effective to inhibit or prevent the growth of *H. pylori* in a human stomach (claim 8). Kim also teaches a method for prevention and/or treatment of gastritis, duodenal and gastric ulcers caused by infection from *Helicobacter pylori* (see Abstract). The living organism being of lactic acid origin is selected from the group consisting yogurt, buttermilk, cream cheese, and ice cream (claim 12). Further more, as evidenced by Wikipedia online, all major dietary carbohydrates contain glucose, and D-glucose and L-glucose are the two isoforms of glucose, thus a bagel would contain sugar D-glucose. Also as evidenced by Wikipedia online, casein is the predominant phosphoprotein that accounts for nearly 80% of proteins in milk and cheese, and lactose is a sugar which is found most notably in milk. Therefore, any one who eats a toast bagel (nutritional food) with a yogurt (contains live strains of living microorganism *Lactococcus* sp HY 49, *Lactobacillus casei* HY 2782, and *Bifidobacterium longum* HY 8001), and drinks milk (inherently contains lactose and casein) reads on treating disorders associated with infection by *Helicobacter pylori*.

Kim et al (US 6,329,002) do not teach the claimed amount of browning reaction product, or an inhibitor of gastric acid secretion to inhibit *Helicobacter pylori*.

Kim et al (US 6,627,238) teaches that browning reaction that contains sugars such as glucose, fructose, galactose, lactose, and free amino groups from proteins of microorganisms (buttermilk, cream cheese) (col 2, lines 4-10) occurs in foods heated by microwave, food



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containing a dough crust heated in a conventional oven, and food to be baked (col 1, lines 30-35; col 2, lines 50-55) [which reads on any one who eats a toast bagel (nutritional food) with cream cheese (lactic acid origin, contains living microorganism) (animal proteins derived from milk)].

Kodama et al teach inhibiting *Helicobacter pylori* with glycoprotein isolated from milk, dairy products, and meat products, and an inhibitor of gastric acid secretion (see Title, Abstract, [0034, 0044]. Kodama et al also teach that the combination of the glycoprotein and the inhibitor of gastric acid secretion is more effective in eliminating *Helicobacter pylori* [0044].

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to consume the browning reaction product, a toasted bagel, in the invention of Kim et al (US 6,627,238), as a nutritional food, to combine with an active strain of a living microorganism, yogurt, and nutritional food milk, in the invention of Kim et al (US 6,329,002), to prevent and/or treat disorders associated with infection by *Helicobacter pylori*. Since the bagel/yogurt, and milk consumption varies according to people's appetite, age, and weight, the amount of browning reaction product as claimed is a result-effective adjustment in conventional working parameter, which is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use an inhibitor of gastric acid secretion from Kodama et al since Kodama et al teach that the combination of the glycoprotein which contained in the milk and dairy products, with the inhibitor of gastric acid secretion is more effective in eliminating *Helicobacter pylori*. Since both Kim et al (US 6,329,002) and Kodama et al yielded beneficial results in

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inhibiting *Helicobacter pylori*, one of ordinary skill in the art would have been motivated to make the modifications.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that “Kodama teaches nothing of a browning product of a protein and a sugar. A browning product as presently recited and glycoprotein such as that of Kim are very different products as explained in the response of March 22, 2007 and the accompanying Declaration. Therefore, Kodama does not overcome the above-discussed deficiencies of the Kim references” (page 7, 4<sup>th</sup> paragraph).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In addition, no Declaration has been received.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

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### **Conclusion**

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Patricia Leith/

Primary Examiner, Art Unit 1655